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Laparoscopic Versus Open Gastric Bypass: A Randomized Study of Outcomes, Quality of Life, and Costs

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Objective

To compare outcomes, quality of life (QOL), and costs of laparoscopic and open gastric bypass (GBP).

Summary Background Data

Laparoscopic GBP has been reported to be a safe and effective approach for the treatment of morbid obesity. The authors performed a prospective randomized trial to compare outcomes, QOL, and costs of laparoscopic GBP with those of open GBP.

Methods

From May 1999 to March 2001, 155 patients with a body mass index (BMI) of 40 to 60 kg/m^2 were randomly assigned to undergo laparoscopic ($n = 79$) or open ($n = 76$) GBP. The two groups were similar in age, sex ratio, mean BMI, and comorbidities. Main outcome measures included operative time, estimated blood loss, length of hospital stay, operative complications, percentage of excess body weight loss, and time to return to activities of daily living and work. Changes in QOL were assessed using the SF-36 Health Survey and the bariatric analysis of reporting outcome system (BAROS). Operative and hospital costs of the two operations were also compared.

Results

There were no deaths in either group. Mean operative time was longer for laparoscopic GBP than for open GBP, but operative blood loss was less. Two (2.5%) of the 79 patients in the laparoscopic group required conversion to laparotomy. Median length of hospital stay was shorter for laparoscopic GBP patients (3 vs 4 days). The rate of postoperative anastomotic leak was similar between groups. Wound-related complications such as infection (10.5 vs 1.3%) and incisional hernia (7.9 vs 0%) were more common after open GBP; late anastomotic stricture was less frequent after open GBP (2.6 vs 11.4%). Time to return to activities of daily living and work were shorter after laparoscopic GBP than after open GBP. Weight loss at 1 year was similar between groups. Preoperative SF-36 scores were similar between groups; however, at 1 month after surgery, laparoscopic patients had better physical conditioning, social functioning, general health, and less body pain than open GBP patients. At 6 months, the BAROS outcome was classified as good or better in 97% of laparoscopic GBP patients compared with 82% of open GBP patients. Operative costs were higher for laparoscopic GBP patients, but hospital costs were lower.

Conclusions

Laparoscopic GBP is a safe and cost-effective alternative to open GBP. Despite a longer operative time, patients undergoing laparoscopic GBP benefited from less blood loss, a shorter hospital stay, and faster convalescence. Laparoscopic GBP patients had comparable weight loss at 1 year but a more rapid improvement in QOL than open GBP patients. The higher initial operative costs for laparoscopic GBP were adequately offset by the lower hospital costs.

Obesity is a burgeoning healthcare problem in the United States.[1] The prevalence of obesity (body mass index [BMI]$\geq$30 kg/m^2) increased from 12.0% in 1991 to 17.9% in 1998.[2] This trend will likely worsen because more than 25% of American children are obese. Obesity is a well-established risk factor for the development of coronary heart disease, type 2 diabetes, dyslipidemia, and hypertension.[3] Severe obesity also has a profoundly negative impact on a person's perception of his or her health.[4] In addition, in-

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creased death rates from all causes for moderately and severely obese men and women have been reported.[5] The cost of obesity to American society has been estimated at $100 billion annually, inclusive of direct medical costs and lost productivity.[6]

According to the National Institutes of Health Consensus Conference in 1991, surgery, specifically open Roux-en-Y gastric bypass (GBP), is an appropriate treatment for patients with morbid obesity.[7,8] With advances in minimally invasive technology, the laparoscopic approach to GBP was introduced in 1994.[9] Laparoscopic GBP has been reported as a safe alternative to open GBP.[10–12] However, before laparoscopic GBP can be accepted as an alternative to open GBP, the results of laparoscopic and open GBP should be compared in a randomized, controlled trial.

Laparoscopic GBP is a technically challenging operation that requires extensive surgical dissection, transection and restoration of intestinal continuity, and advanced laparoscopic suturing and stapling skills. The seemingly higher degree of complexity of laparoscopic GBP has raised concerns that postoperative complications, specifically anastomotic leak, might be more prevalent in laparascopic GPB than in open GBP. In this randomized study, we sought to evaluate the operative outcome, complications, convalescence, quality of life (QOL), and costs after laparoscopic and open GBP.

PATIENTS AND METHODS

The study was performed with approval of the Institutional Review Board of the University of California, Davis, Medical Center. All patients being evaluated for surgical treatment of morbid obesity were considered for entry into this trial. Patients were considered eligible for the study if their BMI was 40 to 60 kg/m^2, they were 21 to 60 years of age and had failed previous nonsurgical attempts at weight loss. Exclusion criteria were previous obesity surgery, previous gastric surgery, large abdominal ventral hernia, history of deep venous thrombosis (DVT)/pulmonary embolism, and severe cardiovascular, respiratory, hepatic, or renal disease. Written informed consent was obtained from all patients who agreed to undergo randomization. After obtaining consent, patients were randomly assigned to laparoscopic or open GBP by the use of sealed envelopes. Patients were stratified according to a BMI of 40 to 49 kg/m^2 or 50 to 60 kg/m^2 and informed of their treatment groups during their preoperative clinic visit. The maximal allowable difference in the number of patients assigned to the two treatment groups was four.

Surgical Technique

A standardized anesthesia protocol was used for both groups. A single dose of preoperative and postoperative antibiotic was given to both groups. Thigh-length antiembolic stockings and a sequential pneumatic compression devices were placed on both lower extremities before induction of anesthesia for prophylaxis against venous thromboembolism. Laparoscopic GBP procedures were performed by a single surgeon and open GBP procedures were performed by one of two surgeons. For the first 22 operations, two surgeons (N.T.N., B.M.W.) performed all surgeries to standardize the techniques of laparoscopic and open GBP as much as possible. In both groups, a 15- to 20-mL transected gastric pouch was created, a 75-cm Roux limb was constructed for patients with BMI of 40 to 49 kg/m^2, and a 150-cm Roux limb was constructed for patients with BMI of 50 to 60 kg/m^2. The gastrojejunostomy anastomosis was performed with a circular stapler.

Laparoscopic Gastric Bypass

Laparoscopic GBP was performed through five abdominal trocars (three 5-mm, one 11-mm, and one 12-mm). Abdominal insufflation was achieved using a Veress needle to an intraabdominal pressure of 15 mmHg. Patients were placed in a reverse Trendelenburg position. The dissection began directly on the lesser curvature of the stomach to gain entrance into the lesser sac. Initially the circular anvil was placed transorally to perform the gastrojejunostomy, similar to the technique described by Wittgrove et al.[9] We had difficulty with this technique and subsequently switched to placing the anvil transabdominally. Using the transabdominal technique, the anvil of the circular stapler (Premium Plus CEEA 25, U.S. Surgical Corp., Norwalk, CT) was inserted into the stomach through a gastrotomy and brought through the anterior gastric wall 1 cm below the gastroesophageal junction. Multiple Endo GIA II 45 staplers (U.S. Surgical Corp.) were applied adjacent to the anvil to create a 15- to 20-mL gastric pouch.

Patients were then placed in the neutral position for creation of the jejunojejunostomy. The jejunum was divided 30 cm distal to the ligament of Treitz. A stapled end-to-side jejunojejunostomy anastomosis was performed, with the Roux limb length measured as previously stated. In the early part of the trial, the remaining enteroenterostomy defect was stapled closed. However, early postoperative bowel obstruction occurred in two patients, prompting us to change our technique to interrupted suture closure of the enteroenterostomy. In addition, we did not close all mesenteric defects or place "antiobstruction" sutures in the first 15 laparoscopic GBP operations. We subsequently closed all mesenteric defects and routinely placed an antiobstruction suture as described by Brolin.[13]

The Roux limb was tunneled via a retrocolic, retrogastric path and positioned near the transected gastric pouch. The CEEA stapler was inserted through a dilated port site (12 mm) to perform the end-to-side gastrojejunostomy. The anastomosis was reinforced with interrupted sutures using the Endo Stitch (U.S. Surgical Corp.), inspected endoscopically, and tested for air leak. All 10-mm trocar fascial defects were closed.

Open Gastric Bypass

Open GBP was performed through an upper midline incision from the xiphoid process to above the umbilicus. The patient was also placed in reverse Trendelenburg position for exposure of the gastroesophageal region. A Thompson abdominal wall retractor (Thompson Surgical Instruments, Inc., Traverse City, MI) was used to provide exposure. An anterior gastrotomy was created on the stomach, and the anvil of the circular stapler was inserted into the stomach and brought out through the anterior gastric wall 1 cm below the gastroesophageal junction. Multiple ENDO GIA II 45 staplers were applied around the anvil to create a 15- to 20-mL gastric pouch. A stapled jejunojejunostomy anastomosis was performed. The small bowel mesentery, transverse colon mesentery, Petersen hernia defect, and antiobstruction sutures were placed at the appropriate sites. The Roux limb was tunneled along a retrocolic, retrogastric path and positioned near the transected gastric pouch. A circular stapler was positioned through the end of the jejunal Roux limb to create an end-to-side gastrojejunostomy. The anastomosis was reinforced with interrupted sutures, inspected endoscopically, and tested for air leak. The abdomen was closed with running nonabsorbable sutures on the fascia, and the skin was approximated with interrupted sutures.

Postoperative Care

All patients were extubated and transferred to the surgical ward after surgery unless they required ventilatory support or close observation in the intensive care unit. A nasogastric tube was not used routinely in the postoperative period in either group. Postoperative pulmonary care included incentive spirometry and deep-breathing exercises. In both groups, patient-controlled analgesia using intravenous morphine was started in the recovery room. Patients were encouraged to ambulate on the same operative day. A Gastrografin contrast study was performed on the second postoperative day. Clear liquid diet was started after confirmation of an intact anastomosis without evidence of contrast leak or obstruction. Patients were discharged from the hospital when oral fluid was tolerated.

Study Protocol

Outcome Measures

Demographic data, BMI, American Society of Anesthesiology classification, and obesity-related comorbidities were collected and recorded prospectively on a computerized data form (Statview; SAS Institute Inc., Cary, NC). The following parameters were contemporaneously recorded: operative time, length of skin incision, estimated blood loss, number of patients requiring intensive care unit stay, length of hospital stay, early and late (>30 days) complications, early reoperation (<30 days), and weight loss. Operative time was defined as the time from the first skin incision to the final closure of the skin incision. Major wound infection was defined as the presence of purulent discharge affecting greater than 8 cm of the surgical wound or requiring operative debridement. Minor wound infection was defined as erythema or purulent discharge affecting less than 8 cm of the surgical wound. At the 1-month follow-up, patients were asked the length of time they needed to return to activities of daily living (daily household chores and physical activities). At the 3-month follow-up, patients were asked the date they returned to work; unemployed or disabled patients were excluded.

All patients remained in the hospital for at least 3 days after the operation. After discharge, all patients were seen in the outpatient clinic on postoperative day 7, at 1, 3, 6, and 12 months after surgery, and yearly thereafter. Postoperative weight and outpatient complications were recorded at each clinic visit. Follow-up weights were obtained from the same obesity clinic scale. Weight loss was expressed as the mean percentage of excess body weight loss (%EBWL).

Quality of Life

The 36-item Health Survey (SF-36) questionnaire form was administered to all patients in both groups before surgery and at 1, 3, and 6 months after surgery. The SF-36 is a well-validated questionnaire that measures the following eight health concepts: physical functioning (limitations in performance of various physical activities), role-physical (limitations in daily activities as a result of physical health), role-emotional (limitations in daily activities as a result of emotional problems), bodily pain (measures pain-related functional limitations), vitality (measures energy level), mental health (measures the presence and degree of depression and anxiety), social functioning (measures limitations in social functioning), and general health (measures an individual's perception of his or her overall health).[14] The SF-36 scores are standardized, with the worst score being 0 (poor health) and the best score being 100 (good health). The results of the SF-36 scores were compared between groups and with established scores of healthy persons in the United States (U.S. norms).

The bariatric analysis and reporting outcome system (BAROS) was administered at 3 and 6 months after surgery. The BAROS is a simple questionnaire that evaluates three main categories: %EBWL, changes in comorbidities, and the Moorehead-Ardelt QOL.[15] A maximum of 3 points was given for each category. The Moorehead-Ardelt QOL questionnaire assessed self-esteem, physical activity, social life, work conditions, and sexual interest/activity; points were added for positive changes and subtracted for negative changes. Points were also deducted for complications and reoperations from the subtotal scores of the three categories. The BAROS outcome was classified as excellent (>7–9 points), very good (>5–7 points), good (>3–5 points), fair (>1–3 points), and failure (1 point or less).

Costs

The costs for laparoscopic and open GBP were derived from the University of California, Davis, Medical Center's decision support system database so as to provide actual cost data as opposed to patient charge data. Costs in U.S. dollars are reported as mean ± standard deviation (SD). The total costs comprised direct and indirect costs. Direct costs were divided into operative and hospital service costs. Operative service costs included operative time, operative supplies, and postanesthesia care. The extra amortization cost of the laparoscopic equipment was also added to the cost of the laparoscopic operation. Hospital service costs included nursing, pharmaceutical, diagnostic, therapeutic, and other services. Indirect costs were overhead costs such as administrative, finance, housekeeping, payroll, insurance, and employee benefits. The direct costs, indirect costs, and total costs were compared between the two groups for the primary surgical hospital stay.

Statistical Analyses

Data for all patients assigned to laparoscopic or open GBP were analyzed on an intent-to-treat basis. Laparoscopic GBP operations that were converted to open GBP were analyzed as laparoscopic operations. Patients who withdrew consent or who did not undergo GBP were excluded from the analysis.

Continuous data are expressed as the mean ± SD, other nonnormally distributed data are expressed as median with interquartile range. Analyses of differences between groups for demographic and operative data were performed using two-sample *t* tests or Fisher exact tests for categorical data. Mann-Whitney tests were performed for nonparametric data. Repeated measures analysis of variance was used to analyze the mean %EBWL at follow-up. After the initial analysis of variance, a series of stratified models were run to look for significant differences between groups at each time point using unpaired *t* tests. SF-36 scores and Moorehead-Ardelt QOL scores were compared between groups using unpaired *t* tests. Statistical evaluations were performed using standardized software (Statview). $P < .05$ was considered significant. A minimum sample size calculation was performed with the assumption that the mean time to return to activities of daily living was 20 ± 17 days in the open GBP group. A difference of 7 days in the time to return to activities of daily living between the laparoscopic and open GBP groups was considered clinically significant. A minimum of 73 patients in each group was necessary to detect this difference using a two-tailed test with a probability of a type 1 error (α) of .05 and a probability of a type .2 error (β) of .2 (power 80%).

Table 1. PATIENT CHARACTERISTICS

Characteristics	Laparoscopic GBP (n = 79)	Open GBP (n = 76)	*P* Value
Gender			
Female	72	67	NS*
Male	7	9	NS*
Age (years)	40 ± 8	42 ± 9	NS†
Preoperative weight (lb)	289 ± 38	296 ± 44	NS†
Preoperative body mass index (kg/m^2)	47.6 ± 4.7	48.4 ± 5.4	NS†
Previous abdominal surgery	46 (58)	54 (72)	NS*
ASA class			
II	31 (39)	23 (30)	NS*
III	48 (61)	53 (70)	NS*
Comorbidities			
Hypertension	26 (33)	31 (41)	NS*
Sleep apnea	21 (26)	23 (30)	NS*
Gastroesophageal reflux disease	30 (38)	24 (32)	NS*
Dyslipidemia	13 (16)	14 (18)	NS*
Diabetes mellitus	8 (10)	14 (18)	NS*
Osteoarthritis	38 (48)	32 (42)	NS*
Depression	33 (42)	33 (43)	NS*
Stress incontinence	17 (22)	12 (16)	NS*

Numbers in parentheses are percentages.
GBP, Roux-en-Y gastric bypass; ASA, American Society of Anesthesiology.
* Fisher exact test.
† Two-sample *t* tests.

RESULTS

Patient Demographics

Between May 1999 and March 2001, 155 patients were randomly assigned to undergo either laparoscopic (n = 79) or open (n = 76) GBP. The two groups were similar in age, sex ratio, mean BMI, and preoperative comorbidities (Table 1). During the study, 19 eligible patients did not undergo randomization: 13 patients specifically requested laparoscopic GBP and 6 requested open GBP. Two patients randomized to open GBP were excluded from the study after randomization; one patient withdrew informed consent and wanted laparoscopic GBP, and the other patient had hemorrhage from an iatrogenic injury of the spleen that ultimately required splenectomy. GBP was not performed in the latter patient.

Operative Data

Operative data for the two groups are shown in Table 2. The mean operative time of the laparoscopic group was significantly longer than that of the open group ($P < .01$). Two (2.5%) of the 79 patients in the laparoscopic group required conversion to open laparotomy: one patient required revision of the stapled gastrojejunostomy as a result

Table 2. PERIOPERATIVE OUTCOMES

Results	Laparoscopic GBP (n = 79)	Open GBP (n = 76)	*P* Value
Operative time (min)	225 ± 40	195 ± 41	<.001*
Estimated blood loss (mL)	137 ± 79	395 ± 284	<.001*
No. patients requiring intensive care unit stay	6 (7.6%)	16 (21.1%)	.03†
Median length of hospital stay (days)	3 (IQR 1)	4 (IQR 2)	<.001‡
No. patients requiring reoperation	6 (7.6%)	5 (6.6%)	NS†
Return to activities of daily living (days)	8.4 ± 8.6	17.7 ± 19.1	<.001*
Return to work (days)	32.2 ± 19.8	46.1 ± 20.6	.02*

IQR, interquartile range; GBP, Roux-en-Y gastric bypass.
* Two-sample *t* test.
† Fisher exact test.
‡ Mann-Whitney tests.

of failure of the circular stapler and the other patient for inability to insufflate the abdomen safely.

The estimated blood loss was threefold greater in the open group than in the laparoscopic group ($P < .01$). Splenic capsule tears occurred in two patients in the open group. Intraoperative transfusion was required in 3 (3.9%) of the 76 patients in the open group and in none of the laparoscopic group.

After surgery, 6 (7.6%) of the 79 patients in the laparoscopic group and 16 (21.1%) of the 76 patients in the open group required intensive care unit stay. The median length of hospital stay was shorter in the laparoscopic group than in the open group (3 vs. 4 days, $P < .01$). There were no operative deaths.

Complications

Major

Major complications after laparoscopic and open GBP are shown in Table 3. Early reoperation occurred in 7.6% of patients after laparoscopic GBP and 6.6% of patients after open GBP.

In the laparoscopic group, six major complications (7.6%) occurred in six patients. One patient developed an anastomotic leak on postoperative day 6 that was managed by open exploration and drainage. A second patient developed a hypopharyngeal injury from placement of the CEEA anvil transorally;[16] this patient was managed by cervical drainage. Three additional patients developed early postoperative bowel obstruction at the site of the jejunojejunostomy as a result of narrowing of the anastomosis during closure of the enteroenterostomy defect with the endoscopic stapler (two patients) and from angulation of the afferent limb (one patient). All three patients underwent successful laparoscopic revision by creation of a second jejunojejunostomy proximal to the obstruction site. A sixth patient developed postoperative gastrointestinal hemorrhage; reexploration showed intraluminal bleeding at both the gastrojejunostomy and the gastric remnant staple lines.

In the open group, seven major complications (9.2%) occurred in six patients. One patient developed an anastomotic leak. This patient was treated conservatively with nothing by mouth, parenteral nutrition, and antibiotics. A second patient developed a gastric outlet obstruction on the first postoperative day requiring endoscopy. A third patient had a retained laparotomy sponge requiring reexploration for removal of the sponge. This patient subsequently developed a pulmonary embolism on postoperative day 14 after discharge. A fourth patient developed respiratory insufficiency requiring prolonged intubation (>3 days). The remaining two patients developed severe wound infections; one of them required operative debridement.

Minor

Six minor complications (7.6%) occurred in the laparoscopic group and nine (11.8%) occurred in the open GBP

Table 3. MAJOR COMPLICATIONS

Complications	Laparoscopic GBP (n = 79)	Open GBP (n = 76)	*P* Value
Gastrointestinal			
Anastomotic leak	1	1	
Gastric pouch outlet obstruction	0	1	
Hypopharyngeal perforation	1	0	
Jejunojejunostomy obstruction	3	0	
Pulmonary			
Pulmonary embolism	0	1	
Respiratory failure	0	1	
Gastrointestinal bleeding	1	0	
Wound infection	0	2	
Retained laparotomy sponge	0	1	
Total	6 (7.6%)	7 (9.2%)	.78*

GBP, Roux-en-Y gastric bypass.
* Fisher exact tests.

Table 4. MINOR AND LATE COMPLICATIONS

Complications	Laparoscopic GBP (n = 79)	Open GBP (n = 76)	*P* Value
Minor			
Gastrointestinal			
Ileus	1	0	
C. difficile colitis	1	0	
Gastrogastric fistula	0	1	
Leak (asymptomatic)	0	1	
Gastrointestinal bleeding	2	0	
Wound infection	1	6	
Deep venous thrombosis	1	1	
Total	6 (7.6%)	9 (11.8%)	.42*
Late			
Gastrointestinal			
Anastomotic stricture	9	2	
Prolonged nausea/ vomiting	1	2	
Small bowel obstruction	1	0	
Cholelithiasis	3	0	
Ventral hernia	0	6	
Nutritional			
Anemia	0	2	
Protein-calorie malnutrition	1	0	
Total	15 (18.9%)	12 (15.8%)	.52*

GBP, Roux-en-Y gastric bypass.
* Fisher exact tests.

group (Table 4). Minor wound infections occurred in one patient in the laparoscopic group and six in the open group.

Late

Late complications are also listed in Table 4. Anastomotic stricture was more frequent after laparoscopic GBP than after open GBP (11.4% vs. 2.6%, $P = .06$). The mean time interval for development of anastomotic stricture was 44 ± 19 days after surgery. One patient in the laparoscopic group developed an intestinal obstruction from internal herniation of the small bowel through the transverse mesocolon defect at 7 months after surgery. This patient's transverse colon mesentery defect had not been closed at the original operation. Postoperative incisional hernias occurred more frequently after open GBP than after laparoscopic GBP (7.9% vs. 0%, $P = .01$).

Weight Loss

The mean %EBWL for the laparoscopic and open GBP groups is shown in Figure 1. The mean follow-up was 9.6 ± 6.5 (range 1–23) months for the laparoscopic group and 9.6 ± 6.3 (range 1–23) months for the open group. Fifty-four (95%) of the 57 patients who had surgery 1 or more

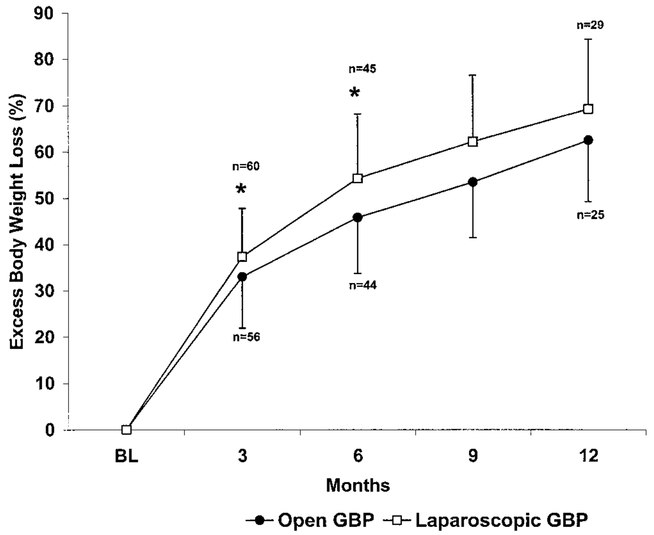

Figure 1. Mean percentage of excess body weight loss (%EBWL) after laparoscopic and open gastric bypass (GBP). *$P < .05$ vs. open GBP (two-sample *t* tests).

years previously were available for follow-up at 1 year. At 12-month follow-up, there was no significant difference in the mean %EBWL between the two groups (68 ± 15% for laparoscopic GBP vs. 62 ± 14% for open GBP, $P = .07$). The mean %EBWL was, however, higher after laparoscopic GBP than after open GBP at 3 months (37 ± 10% vs. 32 ± 10%, $P = .01$) and 6 months (54 ± 14% vs. 45 ± 12%, $P < .01$) after surgery.

Quality of Life

Fifty-four (90%) of the 60 patients in the laparoscopic group and 42 (75%) of the 56 patients in the open group completed the SF-36 assessment at their 3-month follow-up. The preoperative SF-36 scores of laparoscopic and open GBP patients were significantly lower than U.S. norms in seven of eight domains (Table 5). Only mental health was not affected at baseline in both groups. At baseline, SF-36 scores of all eight domains were similar between groups (Fig. 2). At 1 month after surgery, the SF-36 scores in four of the eight domains (physical functioning, social functioning, general health, and bodily pain) were significantly greater in the laparoscopic group than in the open group. At 3 months after surgery, the SF-36 scores in all eight domains had improved in the laparoscopic GBP group and were equal to U.S. norms, although physical functioning was still significantly impaired in the open GBP group (Table 5). By 6 months after surgery, the SF-36 scores on all eight domains in both laparoscopic and open GBP groups were comparable with U.S. norms and were not significantly different between groups.

Assessment of the Moorehead-Ardelt QOL questionnaire at 3 and 6 months after surgery is depicted in Table 6. At 3 months, the scores for sexual interest/activity and work

Table 5. PREOPERATIVE AND POSTOPERATIVE SF-36 SCORES

SF-36 Category	Preoperative Lap. (n = 70)	Preoperative Open (n = 73)	1 Month Lap. (n = 60)	1 Month Open (n = 65)	3 Months Lap. (n = 54)	3 Months Open (n = 42)	U.S. Norms (n = 2,474)
Physical Functioning	46.5 ± 21.3*	40.0 ± 24.4*	60.9 ± 24.7*	46.3 ± 24.7*	80.2 ± 19.1	67.8 ± 26.6*	84.2 ± 23.3
Role-Physical	47.2 ± 40.2*	37.5 ± 37.9*	29.7 ± 39.2*	18.5 ± 32.3*	80.7 ± 32.5	76.8 ± 33.3	81.0 ± 34.0
Bodily Pain	51.0 ± 22.7*	48.7 ± 24.1*	59.2 ± 21.5*	45.1 ± 24.1*	75.1 ± 24.7	68.1 ± 25.6	75.2 ± 23.7
General Health	54.5 ± 21.6*	52.9 ± 22.3*	71.3 ± 18.0	64.0 ± 18.1*	77.2 ± 15.7	72.4 ± 16.5	72.0 ± 20.3
Vitality	38.5 ± 20.0*	36.6 ± 19.9*	45.4 ± 20.5*	39.1 ± 18.9*	65.8 ± 17.7	73.1 ± 95.2	60.9 ± 21.0
Social Functioning	64.4 ± 26.3*	61.6 ± 29.5*	67.6 ± 24.5*	51.9 ± 29.1*	87.3 ± 17.9	74.1 ± 30.0	83.3 ± 22.7
Role-Emotional	49.1 ± 24.4*	45.5 ± 27.2*	78.5 ± 28.2	69.5 ± 33.5*	83.0 ± 29.6	74.6 ± 40.7	81.3 ± 33.0
Mental Health	73.0 ± 15.1	71.9 ± 17.3	76.8 ± 17.4	70.8 ± 19.4	82.9 ± 14.2	75.0 ± 19.2	74.7 ± 18.1

Data are presented as mean ± standard deviation.
* $P < .05$ vs. U.S. norms (two-sample *t* test).

conditions (labor) were significantly higher after laparoscopic GBP than after open GBP. By 6 months, there were no significant differences in any of the five QOL areas. At 6 months, the final BAROS scores were classified as excellent in 25%, very good in 47%, good in 25%, and fair in 3% after laparoscopic GBP and excellent in 11%, very good in 39%, good in 32%, fair in 14%, and failed in 4% after open GBP.

Cost Calculations

Comparison of costs between the groups is shown in Table 7. Operative direct costs were greater for laparoscopic GBP than for open GBP ($4,922 ± $1,927 vs. $3,591 ± $1,000, $P < .01$). Laparoscopic GBP required more Endo GIA reloads than open GBP (13.4 ± 5.7 vs. 5.6 ± 2.7, $P < .01$). Hospital service costs were lower in the laparoscopic group than in the open group ($2,519 ± $1,712 vs. $3,742 ± $3,978, $P = .02$). Specifically, the nursing costs for the laparoscopic group were less than those for the open group ($1,201 ± $821 vs. $1,975 ± $2,773, $P = .03$). There was no significant difference in direct, indirect, or total costs between groups.

DISCUSSION

The results of our study demonstrate that laparoscopic GBP was associated with significantly less operative blood loss, shorter hospital stay, faster recovery, more rapid improvement in QOL but a longer operative time when compared with open GBP. Overall, major, minor, and late complications were comparable between the two groups.

Anastomotic leak is potentially the most serious complication associated with open GBP, with an incidence ranging from 1% to 2%.[8,17] Early reports of laparoscopic GBP had suggested a higher leak rate than open GBP,[10,11] but the seemingly higher leak rate with laparoscopic GBP was likely related to the learning curve of laparoscopic GBP. Wittgrove et al,[11] for example, reported 9 anastomotic leaks (3.0%) in their first 300 laparoscopic GBP procedures but only 2 (1.0%) in their last 200 procedures. In our study, the anastomotic leak rate after laparoscopic GBP (1.3%) was comparable to that of open GBP (2.6%), showing the safety of the laparoscopic technique.

The incidence of wound infections and incisional hernias has been reported to range from 11.7% to 15.8%[8,18] and 8.3% to 20%,[8,19] respectively, after open GBP. Our data showed a significant decrease in the number (1.3% vs. 10.5%) and severity of wound infections after laparoscopic GBP. One patient in the laparoscopic group developed a wound infection at the port site where the circular stapler was inserted; the infection was treated with local wound care and oral antibiotics. In contrast, eight patients in the open GBP group developed wound infections, and all eight required open drainage and a prolonged course of wound care. At a mean follow-up of 9.6 months, 6 (7.9%) of the 76 patients in the open group and none in the laparoscopic group had developed postoperative incisional hernia. We predict that the rate of incisional hernia in the open group is likely to increase with longer follow-up.

Early postoperative bowel obstruction is an infrequent complication after open GBP but has been reported after laparoscopic GBP.[10,12] Schauer et al[10] reported a 1.1% incidence of small bowel obstruction (two jejunojejunostomy obstructions and one internal hernia). Higa et al[12] reported 26 internal hernias (2.5%) after 1,040 laparoscopic GBP operations. Our study shows a higher rate of postoperative bowel obstructions after laparoscopic than after open GBP (5.1% vs. 0%, $P = .12$). In the early part of our trial, we closed the enteroenterostomy defect with the endoscopic stapler, which resulted in narrowing of the jejunojejunostomy in two patients. These complications prompted us to begin closing the enteroenterostomy defect with interrupted sutures. In addition, we did not close the mesenteric defects

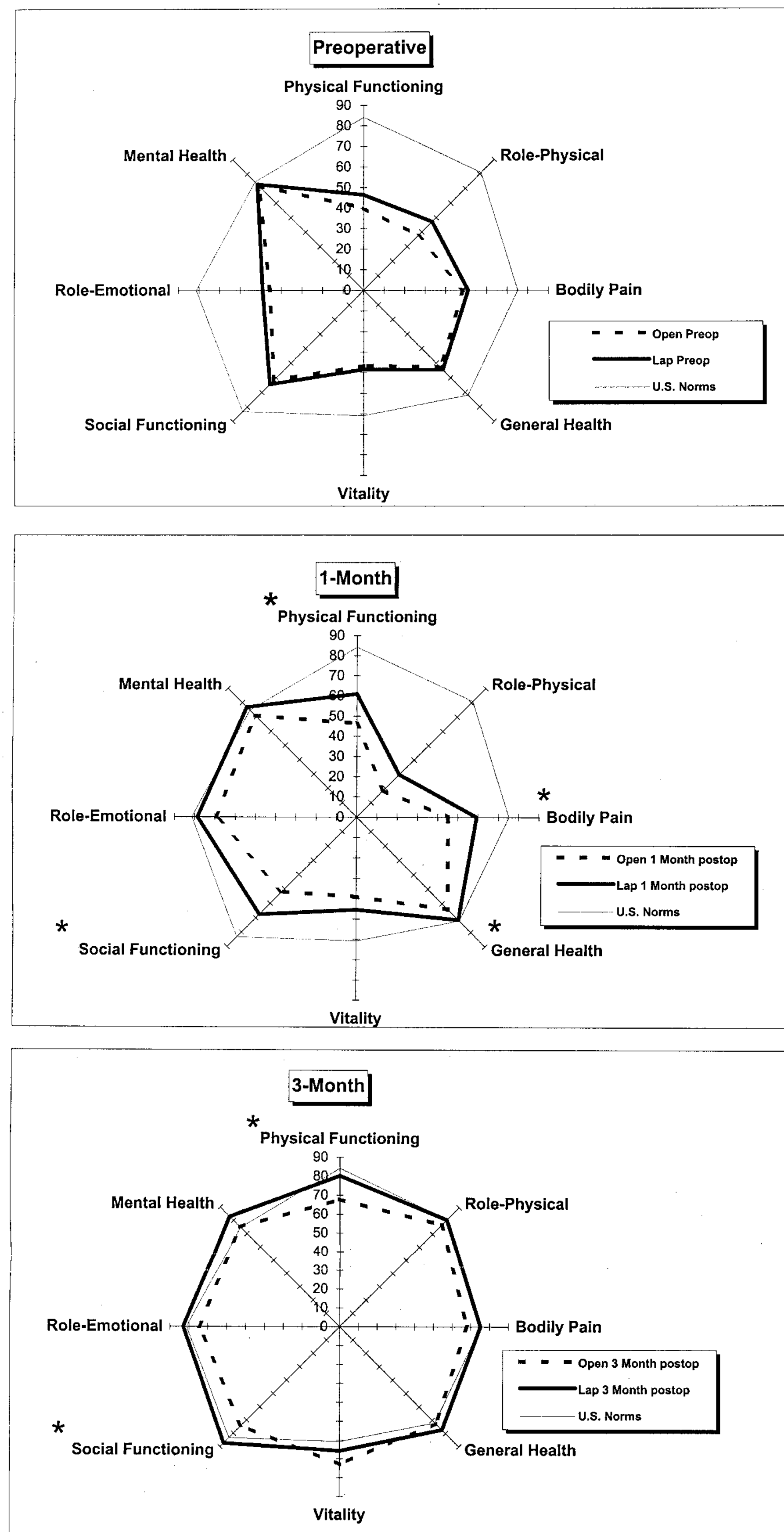

Figure 2. Polar graph of SF-36 scores before surgery and at 1 and 3 months after surgery after laparoscopic and open gastric bypass (GBP). *$P < .05$ laparoscopic vs. open GBP (two-sample t tests).

Table 6. MOOREHEAD-ARDELT QUALITY OF LIFE SCORES

Categories	Score Range	3 Month Follow-up Lap. (n = 47)	3 Month Follow-up Open (n = 36)	6 Month Follow-up Lap. (n = 34)	6 Month Follow-up Open (n = 28)
Self-Esteem	−1 to +1	0.81 ± 0.30	0.73 ± 0.32	0.84 ± 0.27	0.80 ± 0.28
Physical	−0.5 to +0.5	0.48 ± 0.40	0.46 ± 0.44	0.37 ± 0.17	0.34 ± 0.18
Social	−0.5 to +0.5	0.31 ± 0.19	0.24 ± 0.21	0.33 ± 0.19	0.29 ± 0.21
Labor	−0.5 to +0.5	0.24 ± 0.19	0.13 ± 0.29*	0.28 ± 0.21	0.21 ± 0.27
Sexual	−0.5 to +0.5	0.20 ± 0.21	0.09 ± 0.24*	0.26 ± 0.20	0.19 ± 0.26

Score of 0 = same as before surgery; + Score = positive changes; − Score = negative changes.
* $P < .05$ vs. laparoscopic gastric bypass (two-sample *t* tests).

or place the antiobstruction suture in the first 15 laparoscopic patients. As a result, one patient developed an internal hernia through the transverse mesocolon defect and another had a bowel obstruction from acute angulation of the jejunojejunostomy anastomosis. These complications after laparoscopic GBP are technically preventable, and we have not observed any similar complications after having made these changes.

Stricture of the gastrojejunostomy is a frequent complication after open GBP (3–12%).[18,20] Our study showed an 11.4% incidence of anastomotic stricture after laparoscopic GBP versus a 2.6% incidence after open GBP. Our rate of anastomotic stricture after laparoscopic GBP, although greater than that of our open GBP group, is comparable with that of the open GBP series reported by Sanyal et al[20] (12.5%). In our study, the construction of the gastrojejunostomy was standardized using the circular stapler in both groups. The cause of the higher rate of anastomotic stricture in the laparoscopic group is unknown. All patients with anastomotic stricture were successfully treated with endoscopic balloon dilation.

Intraoperative bleeding was less frequent in the laparoscopic group than in the open group. No patient in the laparoscopic group required intraoperative transfusion, compared with 3 (3.9%) of the 76 patients in the open group. However, the incidence of postoperative gastrointestinal bleeding was greater after laparoscopic GBP than after open GBP (3.8% vs. 0%, $P = .24$). The bleeding occurred despite using a 3.5-mm staple height during creation of the gastric pouch and a 2.5-mm staple height on the jejunojejunostomy.

Postoperative venous thromboembolism (DVT and pulmonary embolism) represents an important concern after open GBP. To date, the evidence is inconclusive as to the relative risk of postoperative thromboembolism after laparoscopic GBP. The reported incidence of pulmonary embolism after open GBP with prophylaxis has ranged from .36% to 3.0%.[21–24] Schauer et al[10] reported a .73% postoperative incidence of venous thromboembolism in a prospective series of 275 patients who underwent laparoscopic GBP; Higa et al[12] reported a 0.2% incidence of DVT and a 0.3% incidence of pulmonary embolism in 1,040 laparoscopic

Table 7. COST ANALYSIS

Costs	Laparoscopic GBP (n = 68)	Open GBP (n = 68)	*P* Value
Direct costs	7,478 ± 2,802	7,440 ± 4,661	NS*
Operative costs	4,922 ± 1,927	3,591 ± 1,000	<.01*
Operative time and supplies	4,098 ± 1,538	2,788 ± 674	<.01*
Postanesthesia	504 ± 487	525 ± 382	NS*
Hospital service costs	2,519 ± 1,712	3,742 ± 3,978	.02*
Diagnostic	467 ± 170	609 ± 402	<.01*
Nursing	1,201 ± 821	1,975 ± 2,773	.03*
Pharmaceutical	418 ± 232	579 ± 413	<.01*
Therapeutic	97 ± 249	146 ± 430	NS*
Other	268 ± 213	423 ± 443	.01*
Indirect costs	6,645 ± 2,437	6,765 ± 4,077	NS*
Total costs	14,087 ± 5,237	14,098 ± 8,527	NS*

Data are presented as mean U.S. dollars ± standard deviation. GBP, Roux-en-Y gastric bypass.
* Two-sample *t* tests.

GBP patients. Our results show comparable rates of venous thromboembolism after laparoscopic GBP (1.3%) and open GBP (2.6%), confirming the merit of DVT prophylaxis in both the open and laparoscopic methods of GBP. The optimal methods of prophylaxis for patients undergoing GBP, however, remain unknown.

Although weight loss is an important immediate outcome after GBP, QOL has been shown to be an equally important outcome measure.[4,25] Choban et al[4] reported that severe obesity resulted in a significantly decreased health status in seven of eight domains measured by the SF-36. In their study, during the plateau period of weight loss, surgical treatment improved the scores of all seven domains to the same levels or better than those of U.S. norms. In our study, the SF-36 results also revealed the poor QOL of our patient population at baseline; preoperative SF-36 scores for the physical domains in both study groups were lower than U.S. norms by 49% for physical functioning, by 48% for role-physical, and by 33% for bodily pain. We found that patients' QOL improved more rapidly after laparoscopic GBP than after open GBP. At 1 month, the SF-36 scores were significantly better for laparoscopic GBP patients than for open GBP patients by 31% for physical functioning, 30% for social functioning, 31% for bodily pain, and 11% for general health. At 3 months after surgery, laparoscopic GBP patients continued to have better SF-36 scores for physical functioning (by 18%) and social functioning (by 18%) than open GBP patients.

Other recovery measures in our study were also improved in the laparoscopic group. Patients returned to activities of daily living (8.4 vs. 17.7 days) and work (32.2 vs. 46.1 days) significantly faster after laparoscopic GBP than after open GBP. Schauer et al[10] reported comparable results, with a return to activities of daily living at 9.1 days and return to work at 29.2 days in their series of 275 laparoscopic GBP patients. The faster recovery of laparoscopic GBP patients could be attributed to their higher degree of physical functioning and reduction in bodily pain compared with open GBP patients. The Moorehead-Ardelt QOL questionnaire given at 3 months revealed that all five QOL areas improved from baseline in both groups, but laparoscopic GBP patients had more interest in sexual activity and were able to work more than open GBP patients. Similar to our SF-36 results, these benefits of laparoscopic GBP did not persist when the same questionnaire was administered at 6 months.

The %EBWL at 1 year was similar between the two groups but was greater at 3 and 6 months after laparoscopic GBP than after open GBP. The greater early weight loss after laparoscopic GBP might be attributable to the higher physical functioning at 1 and 3 months after surgery, allowing earlier institution of exercise. The differences in physical activities between the two groups disappeared by 6 months, explaining the equivalent %EBWL between the groups at 1 year.

Before incorporating any laparoscopic procedure into general practice, the economic aspect of the procedure must be evaluated. The value of any new laparoscopic procedure is directly proportional to the outcome and inversely proportional to the costs of the procedure.[26] We found that the operative costs of laparoscopic GBP were 37% greater than those of open GBP because of the more costly nonreusable instruments and longer operative times. Although we used the same type of mechanical stapler for creation of the gastric pouch and jejunojejunostomy in both groups, laparoscopic GBP required more stapler reloads and more costly suturing devices for intracorporeal suturing. The longer operative time is a further disadvantage of laparoscopic GBP, but it varies with the learning curve of this complex operation. Schauer et al[10] reported an overall mean operative time of 260 minutes in 275 laparoscopic GBP cases, but the operative time was only 215 minutes in their last 50 cases. In our study, the mean operative time for our first 50 laparoscopic GBP cases was significantly longer than for our last 29 cases (233 $\pm$ 43 minutes vs. 209 $\pm$ 28 minutes, $P < .01$). The higher operative costs in the laparoscopic group, however, were compensated for by a 33% reduction in hospital service costs, reflecting the shorter hospital stay as well as diminished requirements for nursing, pharmaceutical, and diagnostic services.

We did not include intangible costs in the total costs, which included the amount of postoperative pain, functional and social disability, and lost productivity. Intangible costs were partially quantified in this study using the SF-36 QOL questionnaire, which showed a faster improvement of physical and social disability after laparoscopic than after open GBP. In addition, we had reported in another study that laparoscopic GBP resulted in significantly less postoperative pain than open GBP.[27] The benefit of faster functional recovery, reduced postoperative pain, and gains in productivity from earlier return to work after laparoscopic GBP would seemingly substantiate the cost-effectiveness of this procedure.

Laparoscopic GBP is a challenging and demanding operation. We must emphasize that the results of this study should be weighed in the context of our trial. Our patient population had a BMI between 40 and 60 kg/m^2, and a single surgeon with extensive experience in advanced laparoscopy performed all laparoscopic operations. We have no data regarding the outcomes of laparoscopic approaches in patients with a BMI greater than 60 kg/m^2.

CONCLUSIONS

Laparoscopic GBP accomplishes the same objectives as open GBP but eliminates the large abdominal access incision. It is a safe and cost-effective treatment for morbidly obese patients that offers distinct advantages over the conventional open approach. Laparoscopic GBP was associated with fewer intensive care unit stays, shorter hospital stays, faster recoveries, and an earlier return to work compared with open GBP. This study also shows no increased risk of anastomotic leak with the laparoscopic technique. Additional benefits of laparoscopic GBP include decreased rates of postoperative wound infections and incisional hernias. Laparoscopic GBP, however, required a longer operative time and resulted in a higher anastomotic stricture rate than open GBP.

Assessment of QOL domains showed that laparoscopic and open GBP resulted in a dramatic improvement in the health-related QOL. However, the improvement in QOL was significantly faster after laparoscopic GBP, particularly in the areas of physical functioning, social functioning, bodily pain, and general health. The Moorehead-Ardelt QOL questionnaire showed that laparoscopic GBP patients benefit from earlier interest in sexual activity and ability to work. Weight loss outcomes were comparable between the two groups at the 1-year follow-up, but laparoscopic GBP patients had significantly greater weight loss at 3 and 6 months. We attributed this difference in weight loss to the faster recovery of physical functioning and better general health after laparoscopic GBP. Overall costs were similar for both groups.

Our study shows that laparoscopic GBP is a cost-effective treatment for morbid obesity. Laparoscopic GBP was associated with favorable operative outcomes at comparable costs compared with open GBP. Therefore, in experienced hands, laparoscopic GBP should be considered a viable option for treatment of patients with morbid obesity.

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DISCUSSION

DR. EDWARD E. MASON (Iowa City, Iowa): My congratulations to Dr. Nguyen and his colleagues for an exquisite demonstration of the importance of laparoscopic surgery for obesity. I used pneumoperitoneum in 1953 to prepare patients with giant hernias for hernia repair. In 1954, I used intestinal bypass in two of these patients to try to control weight gain that was causing recurrence of herniation In 1966, the first gastric bypass was performed ina patient with a giant lower abdominal hernia. A year later we used pneumoperitoneum and then repaired her hernia. Later, she regained weight and the hernia recurred.

Dr. Nguyen, you have demonstrated the great advantage of avoiding long incisions in the severely obese. You have the correct sequence by starting with pneumoperitoneum and preventing hernias in the morbidly obese.

My only question, have you considered using a simpler operation? Vertical-banded gastroplasty will provide nearly as great weight control without disrupting the several million years of evolutional development of the digestive tract.

Last month I observed Dr. Wei-Jei Lee in Taipei, Taiwan, perform a laparoscopic vertical-banded gastroplasty. He has performed over 400 of these. They have a small vertical pouch stapled in continuity with one layer of polypropylene mesh collar to control the outlet. The operation appeared to be relatively easy and was accomplished in one hour. It avoids the anastomotic problems. It also avoids the late complications peculiar to gastric bypass operations.

PRESENTER DR. NINH T. NGUYEN (Sacramento, California): Thank you, Dr. Mason, for your comment. We currently are performing only the Roux-en-Y gastric bypass (GBP) operation for treatment of morbid obesity. This decision was based on randomized trials confirming greater long-term weight loss after Roux-en-Y GBP than after vertical-banded gastroplasty.

DR. MICHAEL M. MEGUID (Syracuse, New York): Dr. Nguyen, I appreciate having had the opportunity to read your manuscript. The data you presented really is reflected in the manuscript.

I would like to confine my comments to the very remarkable quality of life indices which were not in the abstract and that you have subsequently presented today. These indices are mainly the normal return to work, the vitality, physical, mental and social functions of the patients randomized to the laparoscopic group. All these indices scored very high and higher than in the open gastric bypass group.

The difference in outcome could be explained by the effect which laparoscopic versus open surgery has on operative surgical stress response, as quantified by diminished sympathetic-neuro-metabolic response and the inflammatory immune response.

Minimally invasive surgical techniques reduce the wound size, as you have demonstrated, but also decrease tissue destruction, blood loss, and postoperative pain. And there is a significantly less initial injury response specifically in the catabolic hormones and a reduction in the acute phase inflammatory responses. Together, these factors hasten recovery, shorten convalescence, reduce fatigue and long-term postoperative morbidity.

It is difficult to understand how the changes in acute surgical stress indices at the time of operation translated into such long-term — three months, six months — improved quality of life indices. Did you have the opportunity to measure any such indices of improved surgical stress at the time of operation and if so, were differences found? I am not aware of long-term surgical stress indicators but I believe such indices should be developed; maybe in relation to muscle function.

Congratulations on a fine study and on persuading patients to be randomized. Thank you for giving me the opportunity to review your manuscript.

DR. NINH T. NGUYEN: I agree with you about the differences of access for the two procedures. Laparoscopic GBP not only eliminates the large abdominal incision but also eliminates handling the bowel and retraction injury to the abdominal wall. In terms of systemic stress response to surgical injury, we also measured the acute phase, cytokine, and metabolic responses to injury in a subset of patients in our study. We are currently analyzing the data. From our initial review, there is a diminished systemic stress response of the laparoscopic group compared with the open group.

Your other question asks if there are indexes that can measure response to injury at three and six months post-GBP. Currently, I do not know of any markers that can assess injury at long-term follow-up.

DR. HARVEY J. SUGERMAN (Richmond, Virginia): I congratulate the authors on their excellent results. Most other series, however, have noted an increased risk of an anastomotic leak with the laparoscopic procedure, averaging between 3 and 5%. In this series, the leak rate was less with the laparoscopic approach, although not significantly. One benefit, perhaps, of a leak after a laparoscopic gastric bypass is that it can often be approached laparoscopically without the risk of the huge open wounds when reoperating in a patient with a leak after an open gastric bypass.

Although these authors' data are excellent, I am aware of several disasters at excellent centers following laparoscopic gastric bypass that harken back to the earlier days of laparoscopic cholecystectomy. The biggest risk appears to be a leak at the jejunojejunostomy that is not seen on an upper GI series and may be diagnosed late. I am also aware of a death in a young woman after a surgeon attended a laparoscopic gastric bypass course and then tried to do one shortly thereafter with major technical errors.

It has been stated on multiple occasions, but needs to be restated again here, that bariatric surgeons must be capable of advanced laparoscopic techniques and be appropriately proctored before tackling this operation and laparoscopic surgeons must be aware of the complexities of operating on severely obese patients. For example, I have also become of a surgeon elsewhere who had five patients develop severe and probably permanent neurological damage as a consequence of persistent vomiting following lap gastric bypass secondary to a thiamine deficiency that should have been totally preventable.

In this regard the authors did note a significantly higher risk of gastrojejunal stenosis following the laparoscopic gastric bypass that they presumed to be a consequence of the reinforcing Lembert sutures used over the EEA anastomosis to prevent a leak.

How were these patients managed? Was there an aggressive approach to endoscopic dilatation? How many times did the patients require dilatation? And did any of these patients develop a peripheral neuropathy or encephalopathy?

It is gratifying to note that the authors are now closing all potential internal hernia defects — after they had one incarcerated internal hernia. Did they approach this laparoscopically? How many of their other patients are "out there" with a risk of an internal hernia? We have had several of these despite closing these defects, and have been successful in several cases reducing the hernia and closing the defect laparoscopically.

It was surprising to see that the costs were not higher with the laparoscopic approach. A likely explanation for this may have been that the authors used most of the same stapling devices for the open gastric bypass procedures, which may have inappropriately inflated the costs for the open approach. They also kept their open patients in the hospital longer, four days on average, than do most of us. Furthermore, they still have more complications in their open patients than most surgeons, with a higher blood loss, a retained laparotomy pad and a prolonged respiratory failure patient.

As the authors separated their patients into BMI 40to 50 and 50 to 60 groups, were there any significant differences in complications between these groups, either open or laparoscopically?

Finally, it is gratifying, as in other studies, to note the improved quality of life in both the open and laparoscopic gastric bypass patients. It was interesting, and supportive of the laparoscopic approach in general, that the quality of life improved quicker and the earlier weight loss was greater in the laparoscopic patients.

It is very difficult to get patients to agree to be randomized between these two approaches. The authors are to be congratulated in "pulling off" this very difficult trial. Thank you.

DR. NINH T. NGUYEN: Thank you, Dr. Sugerman, for your insightful comments.

Anastomotic stricture is a common complication after open GBP (3 to 12%). I do not have an explanation as to why the laparoscopic GBP group in our study had a higher rate of anastomotic stricture than the open GBP group. We standardized our technique for creation of the gastrojejunostomy anastomosis by using the circular stapler in both groups. We managed these stricture complications with endoscopic dilatation under fluoroscopic guidance. A single dilation was sufficient for 90% of the patients.

I agree with you that when patients present with persistent vomiting, they should be treated promptly with endoscopic dilatation if a diagnosis of anastomotic stricture is suspected. In addition, attention to appropriate vitamin supplementation is crucially important to prevent devastating metabolic complications such as neuropathy and encephalopathy.

With regard to the patient who developed a late internal hernia, she was not operated on laparoscopically. In this patient, we identified bowel herniation through the transverse mesocolon defect. We therefore instituted the closure of all mesenteric after our first 15 laparoscopic cases of our trial after your recommendation to do so at the 1999 American College of Surgeons Clinical Congress.

In terms of complications, there were no significant differences in number of complications between patients with morbid or super obesity.

DR. BRUCE D. SCHIRMER (Charlottesville, Virginia): Dr. Nguyen and his associates have done an outstanding job of objectively assessing the relative values of laparoscopic versus open gastric bypass in a prospective randomized study. The results are excellent and are testimony to their surgical skills. They clearly confirm what we laparoscopic bariatric surgeons have suspected — the laparoscopic approach does result in less incisional hernias, less wound infections, and a faster recovery to normal activity. I have several questions for the authors.

In the study you excluded patients with a BMI over 60, history of deep venous thrombosis, home oxygen use, and a history of myocardial infarction. Were such patients ever offered surgery outside the protocol and was it ever laparoscopic?

Their DVT prophylaxis consisted of only SCD boots. We have found that this plus standard heparin was ineffective in totally prophylacting against deep venous thrombosis and pulmonary embolism in our open series. Do you have any comments?

Finally, what effect has your laparoscopic experience had on your technique of open gastric bypass?

I have one last comment. And that is to praise the Program Committee of this Society for the placement of this paper so prominently in the program. The severely obese patient population has long been discriminated against socially, and unfortunately, in the past, medically and surgically. Times and attitudes change — in this case, obviously for the better.

Dr. Ninh T. Nguyen: Thank you, Dr. Schirmer, for your comments. We had strict exclusion criteria in our study patients. Laparoscopic GBP, unlike other laparoscopic operations, requires prolonged CO2 pneumoperitoneum that potentially could have had adverse effects on cardiac function, intraoperative pulmonary mechanics, intraabdominal blood flow, and intraoperative femoral venous blood flow. Therefore, we excluded patients with a previous history of myocardial infarction, deep venous thrombosis (DVT)/pulmonary embolism, or a history of severe respiratory, hepatic, or renal disease. Patients excluded from the trial were offered only conventional open GBP.

In answering your question about DVT prophylaxis, there is still controversy as to the best methods of DVT prophylaxis. In our study, we used a combination of stockings (TED) and sequential compression devices (SCD). We used the Caprini protocol to evaluate each patient by determining the number of his/her risk factors for development of DVT. Patients with 2 to 4 risk factors received TED + SCD. Patients with more than 4 risk factors received both heparin and TED + SCD. The best heparin dose in obese patients, however, is controversial.

Dr. Gerald M. Fried (Montreal, Quebec, Canada): I would like to ask, since this operation is technically demanding; the results that you showed are excellent, I wonder if you could give us some information about the learning curve. How many surgeons were involved in the conduct of the laparoscopic component of the study and how many procedures had they done before you embarked on this randomized controlled trial?

Dr. Ninh T. Nguyen: Thank you for your comment. The issue of the learning curve of laparoscopic GBP is an important question. I believe that there is a steeper learning curve for this operation than for any other commonly performed laparoscopic operation. The learning curve of laparoscopic GBP is directly related to the experience of surgeons performing the procedure. We had performed 30 laparoscopic gastric bypasses before starting our trial. From our perspective, we had jumped a major hurdle by learning all technical aspects of this operation after performing 25 laparoscopic GBP cases. After these 25 cases we continued to make small refinements to the procedure.

Dr. Johannus Jeekel (Rotterdam, The Netherlands): The most frequent long-term complication after surgery is in fact the incisional hernia, 10 to 20%. You indicated that there was a significant decrease in the incidence of incisional hernia. How was the incision made? And did you include the cost consideration?

Dr. Ninh T. Nguyen: Thank you for your comments. Open GBP was performed through a vertical, upper midline incision from the xiphoid process to above the umbilicus. Our incisional hernia rate was 8% in the open GBP group and 0% in the laparoscopic GBP group. We predict that the rate of incisional hernia rate in the open group will likely increase with longer follow-up. In evaluation of costs between groups, we did not take into account the costs required for repair of these incisional hernia complications. I agree with your comment and believe that the costs for open GBP would have been higher if the costs for repair of incisional hernias and treatment of wound infections had been added to the costs of open GBP.